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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,168	12/14/2001	Hsi Liu	6395-61666	9437

7590 04/22/2003

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[REDACTED] EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
1645	8

DATE MAILED: 04/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

*File Copy*

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/017,168	LIU ET AL.
	Examiner Vanessa L. Ford	Art Unit 1645

-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 06 June 2002.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) \_\_\_\_\_ is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) 1-36 are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) All b) Some \* c) None of:  
1. Certified copies of the priority documents have been received.  
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____                                    |

**DETAILED ACTION**

**Election/Restriction**

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group I      Claims 1-16, 27-28 and 30-31 drawn to a method of detecting the presence of *Treponema pallidum* or anti-treponemal antibodies in a biological sample, classified in class 435, subclass 7.22. Further election of a single sequence is required.
- Group II     Claims 17-18, 23-26, 32-33 and 35-36 are drawn to an isolated *Treponema pallidum* acidic repeat protein or immunogenic fragment, immunogenic composition and kit, classified in class 530, subclass 388.6. Further election of a single sequence is required.
- Group III    Claims 19-22, 29 and 34 are drawn to an antibody, an immunogenic composition and kit, classified in class 424, subclass 151.1. Further election of a single sequence is required.

2. Groups I and (II and III) are product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a material different process of using that product (MPEP 806.05(h)). In the instant case the protein of Group II may be used for a number of different processes that are very much unrelated. For example, the protein of Group II can be used to make antibodies.

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3. Groups II and III are different products. Group II is drawn to an isolated *Treponema pallidum* acidic repeat protein or immunogenic fragment, immunogenic composition and kit. Group III is drawn to an antibody, an immunogenic composition and kit. The inventions are patentably distinct, each from the other, because they are different structurally and functionally.

4. A. In the event applicant elects Group I, claims 1-16, 27-28 and 30-31, applicant is required to elect a single sequence. Claims 1-16, 27-28 and 30-31 recited distinct sequences based on structural differences and are patentably distinct one from another.

B. In the event that applicant elects Group II, claims 17-18, 23-26, 32-33 and 35-36 applicant is required to elect a sequence. Claims 17-18, 23-26, 32-33 and 35-36 recite distinct SEQ ID Nos., based on structural differences patentably distinct one from another.

C. In the event that applicant elects Group III, claims 19-22, 29 and 34, applicant is required to elect a single sequence. Claims 19-22, 29 and 34 recite distinct SEQ ID Nos., based on structural differences patentably distinct one from another.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. Because these inventions are distinct for the reasons given and have acquired a separate status in the art because of their recognized divergent subject matter as shown by their different classification, restriction for examination purposes as indicated is proper. Moreover, in the absence of restriction it would place an undue search and examination burden on the examiner.

6. Applicant is advised that the reply to this requirement to be complete must include an election of invention to be examined even though the requirement be traversed (37 CFR 1.143).

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7. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford  
Biotechnology Patent Examiner  
October 24, 2002



LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER